



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SAMSUNG MEDISON CO., LTD.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

March 26, 2015

Re: K150478
Trade/Device Name: A35 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 23, 2015
Received: February 24, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". To the right of the signature, there is a small, faint, rectangular watermark or logo that appears to contain the letters "FDA".

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150478

Device Name

A35 Diagnostic Ultrasound System

Indications for Use (Describe)

The A35 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Peripheral vessel.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: A35 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 5, 6, 7, 8, 9, 10, 11
	Abdominal (See Note 12)	P	P	P	P	P	Note 1	Notes 2, 4, 7, 8, 9, 10, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Note 2, 5, 6, 7, 8, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 10, 11
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Cardiac	Intra-luminal							
	Other (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
Peripheral Vessel	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C2-6IC for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (See Note 12)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CF4-9 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Abdominal (See Note 12)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 2, 7, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339 (C5-8); E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: EC4-9IS for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 10
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 10
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 10
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 10
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L4-7 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Cardiac	Intra-luminal							
	Other (spec.) (See Note 13)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M,

Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L5-13IS for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Cardiac	Intra-luminal							
	Other (spec.) (See Note 13)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L7-16IS for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Cardiac	Intra-luminal							
	Other (spec.) (See Note 13)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: P2-4BA for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V2-6 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 4, 7, 8
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 8
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW2.0 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW4.0 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric					P		
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic					P		
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult					P		
	Cardiac Pediatric					P		
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel					P		
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW6.0 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric					P		
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic					P		
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult					P		
	Cardiac Pediatric					P		
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel					P		
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112339; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA1-7A for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: SC1-6 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: EA2-11B for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	N	N	N		N	Note 1	Note 2, 7, 10
	Abdominal (See Note 12)	N	N	N		N	Note 1	Note 2, 7, 10
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 10
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 10
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)	N	N	N		N	Note 1	Note 2, 7, 10
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: VR5-9 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L5-13/50 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2, 7, 9, 10, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 7, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 7, 9, 11
Cardiac	Intra-luminal							
	Other (spec.) (See Note 13)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-14A for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Cardiac	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.) (See Note 13)							
	Cardiac Adult							
Peripheral Vessel	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16A for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Cardiac	Intra-luminal							
	Other (spec.) (See Note 13)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LS6-15 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
Cardiac	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 7, 9, 11
	Intra-luminal							
	Other (spec.) (See Note 13)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K142466; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CV1-8A for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V4-8 for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: DP2B for use with A35

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 12)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143264; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual /Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Note 11: Spatial Compound Imaging

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNG MEDISON CO., LTD.
42, Teheran-ro 108-gil, Gangnam-gu,
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Data Prepared: January 23, 2015

2. Name of the device:**Common/Usual Name:**

Diagnostic Ultrasound System and Accessories

Proprietary Name:

A35 Diagnostic Ultrasound System

<u>Classification Names:</u>	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Identification of the predicate or legally marketed device:

- ACCUVIX A30 Diagnostic Ultrasound System (K112339)
- WS80A Diagnostic Ultrasound System (K143089)
- H60 Diagnostic Ultrasound System (K143264)
- UGEO PT60A Diagnostic Ultrasound System (K142466)
- SONOACE R7 Diagnostic Ultrasound System (K133505)

4. Device Description:

The A35 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging, PW/CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real-time 4D imaging mode), Elastoscan Mode or as a combination of these modes. The A35 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The A35 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

5. Intended Uses:

The A35 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Peripheral vessel

6. Technological Characteristics:

The A35 is substantially equivalent with respect to safety, effectiveness, and functionality to the ACCUVIX A30 Diagnostic Ultrasound System (K112339), WS80A Diagnostic Ultrasound System (K143089), H60 Diagnostic Ultrasound System (K143264), UGEO PT60A Diagnostic Ultrasound System (K142466) and SONOACE R7 Diagnostic Ultrasound System (K133505).

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

These are described in detail in the technological characteristics comparison table as below.

<Change list>

A35	V3.01	Remarks																								
Model Name	• Change of model name in the V3.01																									
Clinical application	• No addition	The clinical application was described in more detail.																								
Operation of modes	• No addition																									
Applied transducers	<ul style="list-style-type: none"> • Addition of 12 transducers : CA1-7A, SC1-6, EA2-11B, VR5-9, L5-13/50, LA3-14A, LA3-16A, LS6-15, CV1-8A, V4-8, DP2B 	<table border="1"> <thead> <tr> <th>Transducers</th><th>The previously cleared transducers</th></tr> </thead> <tbody> <tr> <td>CA1-7A</td><td>K143089</td></tr> <tr> <td>SC1-6</td><td>K143089</td></tr> <tr> <td>EA2-11B</td><td>None</td></tr> <tr> <td>VR5-9</td><td>K143089</td></tr> <tr> <td>L5-13/50</td><td>None</td></tr> <tr> <td>LA3-14A</td><td>K143089 (L3-12A)</td></tr> <tr> <td>LA3-16A</td><td>K143089</td></tr> <tr> <td>LS6-15</td><td>K142466</td></tr> <tr> <td>CV1-8A</td><td>K143089</td></tr> <tr> <td>V4-8</td><td>K143089</td></tr> <tr> <td>DP2B</td><td>K143264</td></tr> </tbody> </table>	Transducers	The previously cleared transducers	CA1-7A	K143089	SC1-6	K143089	EA2-11B	None	VR5-9	K143089	L5-13/50	None	LA3-14A	K143089 (L3-12A)	LA3-16A	K143089	LS6-15	K142466	CV1-8A	K143089	V4-8	K143089	DP2B	K143264
Transducers	The previously cleared transducers																									
CA1-7A	K143089																									
SC1-6	K143089																									
EA2-11B	None																									
VR5-9	K143089																									
L5-13/50	None																									
LA3-14A	K143089 (L3-12A)																									
LA3-16A	K143089																									
LS6-15	K142466																									
CV1-8A	K143089																									
V4-8	K143089																									
DP2B	K143264																									
SW Features	<p>Additional software features cleared on the predicate devices have been added.</p> <ul style="list-style-type: none"> • SW Features Software improvements migrated from predicate device as below. <table border="1"> <thead> <tr> <th>SW Features</th><th>The previously cleared SW Features</th></tr> </thead> <tbody> <tr> <td>Volume IT</td><td>K143089</td></tr> <tr> <td>FRV</td><td>K143089</td></tr> <tr> <td>Stereo cine (5D Cine)</td><td>K143089</td></tr> <tr> <td>Stress Echo, Strain</td><td>K133505</td></tr> </tbody> </table>	SW Features	The previously cleared SW Features	Volume IT	K143089	FRV	K143089	Stereo cine (5D Cine)	K143089	Stress Echo, Strain	K133505	<p>Description of S/W Features</p> <ul style="list-style-type: none"> • Volume IT: Volume IT provides to calculate the Thickness of IT (Intracranial Translucency) at the sagittal view by acquiring the 3D ultrasound data of a fetus. This feature locates mid-sagittal view and tests the fetus for spina bifida. In normal fetuses the fourth cerebral ventricle presents as an intracranial translucency (IT) parallel to the NT, while in fetuses with open spina bifida there may be absence of the IT. • FVR: This function allows realistic visualization of 3D Volume Data by global illumination technique. This semitransparent rendering technique is useful for detecting morphological abnormalities or malformations of fetuses. • Stereo cine (5D Cine): Generate a 3D Cine image, and save it to portable media such as a USB device. • Stress Echo: It provides functions to support cardio-vascular application. It's for diagnosis of heart moving, using by agents or exercises. • Strain (including TMAD): It provides functions to support cardio-vascular 														
SW Features	The previously cleared SW Features																									
Volume IT	K143089																									
FRV	K143089																									
Stereo cine (5D Cine)	K143089																									
Stress Echo, Strain	K133505																									

A35	V3.01	Remarks
		application. It's for diagnosis of heart moving, using by motion vector.
HW Features	<ul style="list-style-type: none">• Change of Monitor size (21.5 inch → 23 inch)	

<Technological Characteristics Comparison Table>

Feature / Characteristics	The subject device	The predicate devices				
	A35	ACCUVIX A30 (K112339)	WS80A (K143089)	H60 (K143264)	UGEO PT60A (K142466)	SONOACE R7 (K133505)
Indication for Use						
- Fetal/Obstetrics	✓	✓	✓	✓	✓	✓
- Abdominal	✓	✓	✓	✓	✓	✓
- Gynecology	✓	✓	✓	✓	✓	
- Pediatric	✓	✓	✓	✓	✓	✓
- Small Organ	✓	✓	✓	✓	✓	✓
- Neonatal Cephalic	✓	✓	✓	✓		✓
- Adult Cephalic	✓	✓	✓	✓	✓	✓
- Trans-rectal	✓	✓	✓	✓	✓	✓
- Trans-vaginal	✓	✓	✓	✓	✓	✓
- Musculo-skeletal (Conventional)	✓	✓	✓	✓	✓	✓
- Musculo-skeletal (Superficial)	✓	✓	✓	✓	✓	✓
- Urology	✓	✓	✓	✓	✓	
- Cardiac Adult	✓	✓	✓	✓	✓	✓
- Cardiac Pediatric	✓	✓	✓	✓	✓	✓
- Peripheral vessel	✓	✓	✓	✓	✓	✓
Scanhead Types						
- Linear Array	✓	✓	✓	✓	✓	✓
- Curved Linear Array	✓	✓	✓	✓	✓	✓
- Endocavity	✓	✓	✓	✓	✓	✓
- Phased Array	✓	✓	✓	✓	✓	✓
- Static Probes	✓	✓		✓		✓
Scanhead Frequency						
1.0 ~ 20.0 MHz	✓	✓	✓	✓	✓	✓
Modes of Operation						
- B-mode	✓	✓	✓	✓	✓	✓
- M-mode	✓	✓	✓	✓	✓	✓
- Pulsed wave (PW) Doppler	✓	✓	✓	✓	✓	✓
- Continuous wave (CW) Doppler	✓		✓	✓		✓
- Color Doppler	✓	✓	✓	✓	✓	✓
- Power Amplitude Doppler	✓	✓	✓	✓	✓	✓
- Tissue Harmonic Imaging	✓		✓	✓	✓	✓
- 3D/4D imaging mode	✓	✓	✓	✓		✓
- Combined modes	✓	✓	✓	✓	✓	✓
Safety & EMC Compliance						
- IEC 60601-1	✓	✓	✓	✓	✓	✓
- UL 60601-1						
- CSA C22.2 No.601.1						

Feature / Characteristics	The subject device A35	The predicate devices				
		ACCUVIX A30 (K112339)	WS80A (K143089)	H60 (K143264)	UGEO PT60A (K142466)	SONOACE R7 (K133505)
- IEC 60601-2-37	√	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√	√
Acoustic Output Display Standard						
Track 3	√	√	√	√	√	√
Patient Contact Materials						
Tested to ISO 10993-1	√	√	√	√	√	√
Functionality						
- Quick Scan (Q Scan)	√	√	√	√	√	√
- DMR+(Dynamic MR Plus)	√	√	√	√	√	√
- Spatial Compound Imaging	√	√	√	√	√	√
- Auto IMT(Auto IMT+)	√	√	√	√	√	√
- Elastoscan	√	√	√	√		√
- Panoramic	√	√	√	√		√
- 3D Imaging (Volume Data Acquisition)	√	√	√	√		√
- 3D Imaging presentation	√	√	√	√		√
3D Cine/4D Cine /Stereo Cine(5D Cine)	√	√	√	√		
- 3D Rendering MPR(Multi Planer Render)	√	√	√	√		√
- 3D XI MSV(Multi Slice View), Oblique View	√	√	√	√		√
- 3D MXI Volume Slice, Mirror View	√	√	√			
Volume CT	√	√	√			
- 3D MagiCut	√	√	√	√		√
- Volume Calculation (VOCAL, XI VOCAL)	√	√	√	√		
- XI STIC	√	√	√	√		
- HDVI	√	√	√			
- FRV	√		√			
- Volume NT	√	√	√	√		
Volume IT	√		√	√		
- ADVR (Screen DVR)	√	√	√			
- Strain	√					√
- Stress Echo	√					√

7. A brief discussion of the bench and non-clinical tests conducted on the subject device

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The A35 and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

Summary of Clinical Tests:

Not applicable. The subject of this submission, A35, did not require clinical studies to support substantial equivalence.

8. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the A35 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary